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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,929	08/29/2006	Patrick Leahy	KEL01 P-146	6150

28101 7590 11/13/2008  
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EXAMINER
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MCEVOY, THOMAS M

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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11/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,929	<b>Applicant(s)</b> LEAHY, PATRICK	
	<b>Examiner</b> THOMAS MCEVOY	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/2005</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Claims 4 and 5 can not be renumbered to claims 5 and 4, respectively. Appropriate correction is required. Please note that a claim which depends from a dependent claim can not be preceded by a claim that does not depend from the same dependent claim (MPEP 608.01(n)).

Claim 9 is objected to because of the following informalities: "1 claim in" should be changed to --claim1 in--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

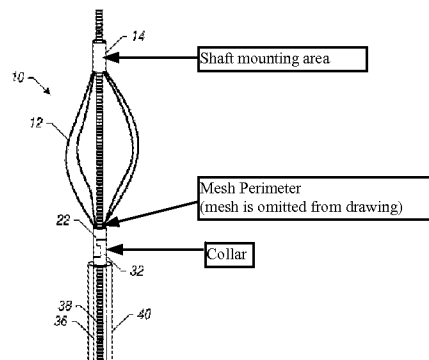
3. Claims 1-15, 17-20 and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kónya et al. (US 6,368,338).

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Regarding claims 1, Kónya et al. disclose a device capable of use in parietal surgery, the device comprising a body 40; a parietal surgical implant 10 (capable of implanting in a cavity wall), the parietal surgical implant being locatable in a collapsed state about or within the body (Figure 15), the parietal surgical implant being adapted to be displaceable between the collapsed state and an expanded state (Figure 14 vs. Figure 15); and means for expanding the parietal surgical implant from the collapsed state into the expanded state (e.g., shaft 36, connection members 22 and 32). Regarding claims 2-4, the parietal surgical implant is locatable within the body (Figure 19); and a sleeve 40 is provided for retaining the parietal surgical implant within the body in the collapsed state, the sleeve is operable to expose the parietal surgical implant (Figure 14 vs. Figure 15). Regarding claims 5-7, the proximal end of sleeve 40 and shaft 36 may be held as handles to effect displacement thus acting as actuators (col. 17, lines 18-32 and col. 20, lines 6-9). Regarding claim 8, the proximal end of shaft 36 (the actuator) is slidably engaged with the body 40. Regarding claim 9, the parietal surgical implant comprises a mesh having a mesh perimeter (at proximal end of mesh) and a shaft mounting area, the mesh being mounted to a shaft (the mesh is mounted to the shaft 38 at its distal end via collar 14); and the expanding means 36/32 is slidably mounted about the shaft, the expanding means being displaceable towards the mesh, in order to urge the mesh towards the expanded state (shaft 36 can be moved distally, towards the mesh to deploy the implant; col. 16, line 64 to col. 17, line 6). Regarding claims 10 and 11, the expanding means comprises a collar 32 slidably mounted about the shaft, and a plurality of arms 12 mounted between the collar and an arm mounting position of the mesh 16 (the arms are mounted to many positions of the mesh; some of which are between the collar and the shaft mounting area

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which is at the distal end of the mesh), the arm mounting position being spaced apart from the shaft mounting area (Figure 17). Regarding claims 12 and 13, the some of the mounting positions of the arms are at or near the mesh perimeter and spaced apart (as evident from Figure 19 for example), which are also spaced from the shaft mounting area (the distal end of the mesh at collar 14). See diagram below:



4. Regarding claim 14, the shaft mounting area is substantially centrally located within the mesh as seen in Figure 20. Regarding claim 15, the mesh can be expanded to a spherical shape or even further to a disc-like shape (Figures 6 and 22). The arm mounting positions as explained above are spaced around the mesh perimeter which is at the proximal end of the mesh. Regarding claim 17, the mesh is separable from the shaft (Figure 21). Regarding claim 18, the mesh and the shaft are capable of press fit engagement. Regarding claim 19, the shaft can be formed from nitinol (col. 14, lines 44-46). Regarding claim 20, collar 14 may be regarded as an abutment against which the mesh is seated. Regarding claim 24, the Kónya et al. device is capable of being reused and therefore a second implant may be regarded as a replacement part. Regarding claims 25-27, see claims 9-11 above. Regarding claims 28 and 29, Kónya et al. disclose that the implant can be secured to a surgical site (Figure 21).

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5. Claims 1, 9, 16, 21, 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gifford et al. (US 6,375,668 B1).

Regarding claims 1, 9 and 16, Gifford et al. disclose a device capable of use in parietal surgery, the device comprising a body 8; a parietal surgical implant 30 (capable of implanting in a cavity wall), the parietal surgical implant being locatable in a collapsed state about or within the body, the parietal surgical implant being adapted to be displaceable between the collapsed state and an expanded state (Figure 4 vs. Figure 5); and means for expanding the parietal surgical implant from the collapsed state into the expanded state (e.g., shafts 10 and 60). Regarding claims 9 and 16, the implant has a mesh with a perimeter and a shaft mounting area 52 (Figure 2). The expanding means 10 is slidable about shaft 60. The shaft and expansion means can be pulled towards each other to effect expansion of the mesh (col. 6, lines 40-60). Regarding claim 21, the Figure 11-13 embodiment shows an implant which is mounted about the body 70 which is expanded by an inflatable balloon mounted on the body (col. 7, lines 32-37). Regarding claim 23, the implant can comprise a biodegradable material (col. 6, line 1).

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731